UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS) (RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF IT MOTION TO EXCLUDE THE OPINIONS OF DR. JOHN KORNAK

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The PSC respectfully files this motion to exclude the testimony of John Kornak Sutcliffe, Ph.D., a biostatistician. The PSC incorporates as if set forth in entirety the legal standards set forth in The Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard ("Rule 702 Standard Brief").

I. Introduction.

On May 15, 2024, scientists from the National Institutes of Health (NIH), National Institute for Environmental Health Sciences (NIEHS) and National Cancer Institute (NCI)—scientists that J&J previously called "preeminent"[1]—published a study entitled O'Brien, *et al*., *Intimate Care Products and Incidence of Hormone Related Cancers: A Quantitative Bias Analysis*, J. Clin. Oncol., 00:1-15 (May 15, 2024) ("O'Brien 2024"). (Ex. 1.) The O'Brien 2024 study arose from the NIH "Sister Study," a long-running cohort examining cancer. The study "supports a positive association between genital talc use and ovarian cancer consistent with previous studies." *Id*. at 13.

After publication, the NIH highlighted O'Brien 2024 as a study that **"provides compelling evidence that genital talc use is associated with an increased risk of ovarian cancer."** (Ex. 2, NIH/NIEHS Environmental Factor, (Jun. 2024), at 1.) It also noted that O'Brien 2024 found the "strongest associations observed for frequent use and long-term users and for use during the reproductive years." *Id.* at 2. According to the

[1] See Doc. 32026 at 11.

NIH, O'Brien 2024 "incorporates rigorous adjustments for biases" through its "especially unique" methodology called "quantitative bias analysis." *Id*. at 1.

O'Brien 2024's authors explained that, as part of their quantitative bias analysis, the authors consulted a statistical process called "multiple imputation," which is a method designed to deal with missing data. (Ex. 1, O'Brien 2024 at 4.) Accompanying the O'Brien 2024 publication was an invited editorial that also concluded that its quantitative bias analysis and recall bias analyses were reliable, and that the data derived from the use of those methods supported a "significant increase in ovarian cancer risk." (Ex. 3, Harris, et al., *Epidemiologic Methods to Advance Our Understanding of Ovarian Cancer Risk*, J. Clin. Oncol 001:3 (May 15, 2024), at 1.)

Within days of O'Brien 2024's publication, J&J's attorneys employed an expert headhunting outfit called "Cornerstone," which led the attorneys to John Kornak, Ph.D., a biostatistician. Kornak initially wrote his report just three days after being contacted and continued to revise his report after his completion of his read of the O'Brien study. (Ex. 4, Kornak's Invoice.)

Kornak's final report is without context or relation to other evidence and scientific literature supporting or refuting causation. (Ex. 5, Expert Report of John Kornak, Ph.D. (May 28, 2024).) Rather, the focus of his report is to relitigate the peer-reviewed statistical methods NIH authors used and fully disclosed—quantitative bias analysis and the multiple imputation methodology. Using non-scientific descriptors that more likely

mirror J&J's legal briefs, Kornak calls the O'Brien 2024 study methods "contrived" and "vacuous," *id.* at 36 ¶ 74, and accuses the NIH authors of "guess[ing]," "assum[ing]," and otherwise manipulating their data, *id*. at 18 ¶ 40. Kornak concluded that the study methods were "flawed and unreliable" and should not have been published. *Id.* at 19 ¶ 42.

Kornak's deposition testimony reveals the dismissive nature of his attack on the methods of this peer-reviewed paper. He flatly disagreed with the entire peer review process and every scientist who reviewed and accepted the paper:

> Q. [O'Brien 2024] went through peer review, true?
>
> A. I mean, it did. **I'm amazed it did. I can't understand how—they must have not had biostatistical review, because that was amazing that that got through without—**

(Ex. 6, Kornak Dep. 106:21–107:3.)

> Q. . . . Is there any possibility in your mind that the peer reviewers could have missed the methodology point of this study, particularly since it's in the title of the article?
>
> **A. Oh, absolutely, I think they did miss it, yeah.**
>
> **Q. Okay. All right. Now, the article, so you think that the peer reviewers and the journal completely missed it?**
>
> **A. Yes, I do. Yeah, I mean, it's—they missed it. I don't know what—I'm surprised that a journal would let that go. I blame it probably on the associate editors for not picking the right range of reviewers, but nobody picked up on the biostatistical problems in this paper.**

Id. at 164:22–165:15.

> Q. I understand, but you've disagreed with the peer reviewers, you've disagreed with the journal, and now you're disagreeing with the NIH, correct?
>
> . . .
>
> **THE WITNESS: You know, what you say explicitly is correct, I'm disagreeing with all of them—**

Id. at 174:7–14.

> Q. And you claim that the authors, the peer reviewers and everybody involved has missed it, right?
>
> A. Sorry, what is it that you're talking about specifically?
>
> Q. The methodology concerns that you identify in your report, Exhibit 1.
>
> **A. They absolutely missed it, yes**

Id. at 166:18–167:2. In fact, he went on to disagree with *every* scientist involved in reviewing O'Brien 2024. *Id.* 399:2–407:5.

Kornak went so far as to suggest that the courtroom, and not the scientific peer review process, might be the place where issues concerning methodology of this study should be resolved:

> Q. Do you agree that, generally speaking, the peer-review process and not the courtroom provides the best mechanism for resolving scientific uncertainty relating to methodologic analysis of complex scientific issues?
>
> A. **Well, it depends** what you mean by "best" here, because what the complex—I don't know if peer review really resolves complex scientific issues. . . .

Id. at 184:23-185:8.

For the reasons set forth below, the Court should exclude Kornak's full throated-attack on the peer-reviewed methods used in O'Brien 2024.

In further support of this motion, the PSC offers a rebuttal report by Elizabeth Stuart, Ph.D., the Chair of the Department of Biostatistics at Johns Hopkins University. (Ex. 7, Rebuttal Expert Report of Elizabeth Stuart, Ph.D. (July 21, 2024).) Unlike Dr. Kornak, Dr. Stuart has published numerous statistical articles on the very same statistical method of "multiple imputation" that Dr. Kornak criticizes. Notably, Dr. Kornak cites Dr. Stuart and her discussion of multiple imputation in support of his analyses.[2] In her rebuttal report, Dr. Stuart states as follows:

> . . . O'Brien et al.'s use of quantitative bias analysis and multiple imputation are appropriate and well considered, allowing the analysis to use all the prospective and retrospective data available and drawing appropriate conclusions regarding the links between genital talc use and ovarian cancer. As indicated and expected given its publication in a top peer-reviewed oncology journal it is an important contribution to the body of literature on the relationship between genital talc use and ovarian cancer and should be included when considering the weight of the evidence regarding such a link.

Id. at 1.

[2] Specifically, Dr. Kornak cites the paper by M. Azur (2011) in his own report at page 19, paragraph 44, footnote 59 (and again in App'x B to his report). As App'x B reveals, Dr. Stuart is an author of the Azur (2011) paper.

II. Background.

To appreciate the spurious nature of J&J's expert's methodologic criticisms of O'Brien 2024, it is important to understand the Sister Study generally, several specific talc use studies derived from Sister Study data, O'Brien 2024's methodology, and, finally, Kornak's report. These are discussed in turn:

A. The Sister Study.

The Sister Study is an NIH cohort of approximately 50,000 women, aged 35–74, who never had breast cancer but who had a sister who had breast cancer.[3] Enrollment in the Sister Study was completed in 2009. It was established to find the causes of breast cancer and to identify risk factors that might help prevent it.

The scientists involved in the Sister Study are amongst the most senior and qualified scientists at NIEHS. The Sister Study was initially established in 2003 by Dr. Dale Sandler and Dr. Clarisse Weinberg, heads of the NIEHS Chronic Diseases Epidemiology Group and NIEHS Biostatistics Branch, respectively.[4] Both Dr. Sandler and Dr. Weinberg appear on many of the Sister Study publications, including O'Brien 2024.[5] In addition, NIH Scientist Katie O'Brien, Ph.D., and Nicholas Wentzensen, M.D.,

[3] Information on the Sister Study is available in Exs. 10, 12, and 1. It is also available online at its web site, https://sisterstudy.niehs.nih.gov/.
[4] Their biographies are attached as Exs. 8 and 9.
[5] Ex. 10, NIEHS, *Research Articles* (list of Sister Study publications), *available at* https://sisterstudy.niehs.nih.gov/English/articles.htm.

Ph.D., have published several papers together on talc and ovarian cancer arising from that cohort.[6]

B. The Gonzalez 2016 study.

Gonzalez 2016 was the first publication based on the Sister Study to consider the relationship between genital talc use and ovarian cancer. (Ex. 11, NL Gonzalez, KM O'Brien, AA D'Aloisio, DP Sandler and CR Weinberg, *Douching, Talc Use, and Risk of Ovarian Cancer*, 27 J. Epidemiology 797 (Nov. 2016).) At the time it was submitted for peer review publication, there were 154 ovarian cancer cases available for study with a median of only 6.6 years of follow-up. *Id*. at 797.

Importantly for the purposes of this motion, the enrollment questionnaire used in Gonzalez 2016 did *not* ask about the lifetime use of talc products, which is an important scientific question in this case. Rather, the participants were asked about only two limited and discrete periods of time—talc use between ages 10–13 years of age, and one year before enrollment. (Ex. 11, Gonzales 2016 at 801, 798; *see also* Ex. 5, Kornak Rep. 5 ¶ 16.)

To illustrate how limited this enrollment question was, the *youngest* Sister Study enrollee (a 35-year-old woman) was asked only about talc use between ages 10–13 and at age 34, but *not* including the 20 years between age 14 and 34. (Ex. 11 at 2 (age range of participants was 35 to 74).) Even more extreme, that means the oldest enrollee, a 74-

[6] Ex. 10.

year-old woman, was asked about use between ages 10–13 and at age 73, but not about talc use in the almost 50 years between ages 14 and 73. Thus, the enrollment questionnaire left decades-wide gaps in talc use and corresponding data. *See also* Ex. 6, Kornak Dep. at 210:5–211:20 (agreeing with description of questionnaire and presence of decade-long data gaps).

Because the women in the Sister Study were *not* initially asked about lifetime talc use, or decades of talc use, the authors did not purport to estimate whether lifetime talc use was associated with cancer risk, nor could they. The authors could only report results suggesting that women were not at increased risk of ovarian cancer after 6.6 years if they used talc a year before enrollment—in their words, "we did not observe an association between *recent* talc use and ovarian cancer risk." (Ex. 11, Gonzales 2016 at 7 (emphasis added).)

C. The 2023 Douching Study.

An attempt to fill the data gaps in genital talc use described in the Gonzalez 2016 was made by the authors of the 2023 "Douching Study." (Ex. 12, K. O'Brien, K. Ogunsina, N. Wentzensen, D. Sandler, *Douching and genital talc use: Patterns of use and reliability of self-reported exposure*, J. Epidemiology, 2023 01:34 (3): 376 (May 2023).)

In this study, the authors reported on the results of a followup questionnaire issued to Sister Study participants in 2017–2019, asking them new questions about "their use of

douche or genital talc over their lifetimes." *Id*. at 376. (The new question is #138 on the new questionnaire, Ex. 13.) As the authors noted, "[b]ecause the enrollment questionnaire did not collect information on use between age 14 and >1 year prior to enrollment, it was possible for a participant to report never use on the enrollment questionnaire and ever use on the follow-up questionnaire without contradicting themself." *Id.* at 378. Even Dr. Kornak agreed that the supplemental questionnaire was designed to solve this problem by closing the data gap. (Ex. 6, Kornak Dep. 212:9–213:13.)

The purpose of the 2023 Douching Study was to "capture patterns of use [including talc] over the life course" and "evaluate the reliability of self-reported data." (Ex. 12, Douching Study at 376.) The authors compared the reliability of the results of the limited, initial enrollment Sister Study questionnaire—which was prospective—with the more comprehensive supplemental questionnaire—which was mostly retrospective. The object was to see whether there was consistency, whether there was a difference between what women reported prospectively and what was reported retrospectively. Ultimately, the results showed that "[c]omparisons across the two questionnaires . . . showed good consistency." *Id*. The authors reported several other findings important to this motion:

- **First**, the authors reported that "genital talc use was most common during ages 20–29," and that the average age at first use was 21.0 years. *Id.* at 378; *see also id.* at 381, Table 2.

These are the very periods not covered by the Sister Study enrollment questionnaire, but *were* covered by the supplemental questionnaire.

- **Second**, the authors reported that there was "good consistency" between the two questionnaires, *id*. at 384, and limited evidence that "recall bias" might affect the data.

- **Third**, because they validated their results, the Douching Study authors felt that finding "will help guide future investigations of the health effects" of talc. *Id*.

Indeed, the Douching Study did guide future investigations: it paved the way to the recent study, O'Brien 2024.

D. The O'Brien 2024 study.

O'Brien 2024, Ex. 1, is the capstone study relevant to this motion. O'Brien 2024 addressed important questions left unresolved by Gonzalez 2016: the foremost of which is, whether in this cohort study, the *long term* use of genital talc was associated with an increased risk of ovarian cancer. The answer was Yes.

To address this important question, the NIH investigators—including all of the same authors from the 2023 Douching Study—used data from the original Sister Study enrollment questionnaire as well as the expanded lifetime talc use information gleaned through the new supplemental questionnaire described above. As the authors noted, the exposure assessment used in O'Brien 2024 included a "mix of retrospective and prospective information, integrating some of the strengths and limitations of each data type." *Id.* at 13. With the expanded lifetime talc use information now available to them, the authors set out their objective:

> Our main objective was to re-evaluate the associations between intimate care product use and incidence of hormone-related cancers, expanding on previous analyses, by incorporating newly diagnosed ovarian and uterine cancers, adding breast cancer as an outcome, **and integrating new data on lifetime use of douche and genital talc.**

Id. at 2 (emphasis added).

While the limitations of the Sister Study enrollment questionnaire were obvious—it simply did not ask for lifetime use during the very times when women were most likely to use genital talc—the NIH authors had to address two issues raised by the new supplemental questionnaire, the one that retrospectively asked about lifetime talc use:

First, there was a concern that some data could be missing: some women who may have filled out the limited questionnaire at enrollment into the Sister Study did not (or could not) fill out the new supplemental questionnaire because, for example, they died of cancer before they could do so. *Id* at 14. "Because the newly acquired exposure data were susceptible to differential missingness by cancer status, we used quantitative bias analysis to estimate effects under several missingness assumptions." *Id*. at 2. Dr. Kornak challenges the study's use of quantitative bias analysis.

Second, there was a concern over recall bias—the possibility that a woman with ovarian cancer would be more likely to recall using talc and thus skew the results in favor of association. The O'Brien 2024 study authors described their intent to take that into account: "When examining the association between genital talc use and ovarian cancer, we additionally evaluated the potential impact of recall bias." *Id*. at 2.

So the authors responsibly identified both issues and set out their two-step plan for analyzing them in their paper. They describe their methods in a lengthy seven-page section, *id*. 2–8, plus a "supplemental methods" appendix, App'x 1. The sections titled "Quantitative Bias Analysis" and "Recall Bias," *id*. at 4, fully describe the methods used to address these issues. With respect to the first step, quantitative bias analysis, the authors provided a detailed plan for addressing "contradictory data," and described a common statistical method, multiple imputation, for dealing with "missingness." *Id*. at 4.[7] With respect to the second step, their "recall bias" plan used various scenarios to "test" the data to determine how recall bias may have affected the results. *Id*. The methods and their statistical analysis for both steps are set forth below.

Quantitative Bias Analysis

The O'Brien 2024 authors identified the multiple imputation statistical method as coming from another published paper by White and Royston. *Id.* at 4, n 32 (paper identified); Ex. 14, White and Royston, *Imputing missing covariate values for the Cox model*, 28 Statist. Med. 1982 (2009).[8] The O'Brien 2024 authors used multiple

[7] Dr. Stuart explained multiple imputation in a published article. Ex. 17, Li, Stuart, & Allison, *Multiple Imputation: A Flexible Tool for Handling Missing Data*, 314 JAMA 1966 (Nov. 10, 2015). "Missing data are common in research. . . . When missing data occur, it is important not to exclude cases with missing information . . . . Multiple imputation better handles missing data by estimating and replacing missing values many times." *Id*. at 1966. In O'Brien 2024, the NIH investigators describe the multiple imputation methods they used. (Ex. 1 at 4 & n.32.)

[8] White and Royston wrote: "Multiple imputation is commonly used to perform statistical inference in the presence of missing data. Unlike simpler imputation methods,

imputation to determine which of the women who did not (or could not) answer the supplemental questionnaire would likely have used talc in their lifetime and which did not. This standard statistical assessment was not based on assumptions or guesses, as Dr. Kornak and J&J would insinuate. Rather, it is based on real answers to the incomplete enrollment questionnaire, which never asked for information on lifetime use.

Said another way, the O'Brien 2024 multiple imputation analysis was based on an objective assessment of multiple sources of data the investigators had collected on each woman, which were statistically correlated with either talc use or talc non-use.

Using that data, and the data on women who had filled out both questionnaires, lifetime genital talc use was associated with a 1.82 relative risk—an 82% increased risk—which number was statistically significant. *Id.* at 12. The risk was even higher in women who were long term users and women who began using in the 20's and 30's (periods not covered in the enrollment questionnaire).

Recall Bias Analysis

As discussed, the NIH authors did not ignore the theoretical possibility that recall bias *might* have inflated the statistically significant positive risk results. They addressed the potential of recall bias head on. *Id.* at 4, App'x 1. Using another clearly-defined methodology (which was also peer-reviewed), they discussed that their data findings

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it can yield inferences that accurately reflect the uncertainty due to the missing data. MI is typically more efficient than complete cases analysis when covariates have missing values." Ex. 14 at 1982.

revealed a significant association between genital talc and ovarian cancer persisted *even if* certain data were "re-cod[ed]" in an effort to address recall bias. *Id*. at 4. The authors described different scenarios that would plausibly accomplish that. For example, "[w]e assumed 25% of ovarian cancer cases" classified as users "were reassigned to be nonusers." *Id.* The authors computed "HRs based on this correction" in their results, and concluded that they were "examples of plausible, yet cautious, estimates of the association" between talc and ovarian cancer. Even after the hypothetical, exaggerated corrections were applied, the results still showed a positive association, consistent with dozens of other studies.

To further test whether recall bias may have been introduced into their study, the authors noted the following:

- **First**, examining only at prospective data, which by definition cannot be subject to recall bias, the risk was still 1.84 (CI, 0.90 to 3.77), a value "consistent with a positive association." *Id.* at 13; *see also* Table A-2.
- **Second**, they noted that there was no increased risk for either breast cancer or uterine cancer—a finding at odds with the suggestion that talc use data collected through the "Quantitative Bias Assessment" (including "multiple Imputation") was infected with "recall bias." *Id.* at 12. *See also* Ex. 3, Harris, at 2 ("the lack of an association between genital powder use and uterine cancer provides additional support that recall bias does not fully explain the genital powder and ovarian cancer association").

Overall Results

In their Discussion section after this two-step analysis, the authors emphasized that the Sister Study cohort showed a consistent elevated risk among all study types—a position that has been highly disputed by J&J in all talc litigation. They wrote:

> Using newly collected data on intimate care product use in a large cohort of US women, we found evidence supporting a positive association between ever genital talc use and incident ovarian cancer.
>
> . . .
>
> Our findings of a positive association between genital talc use and ovarian cancer are consistent with previous studies. Pooled analyses or meta-analyses of case-control studies have produced odds ratios of 1.2–1.4. The HR from a pooled analysis of prospective cohort studies also indicated a positive, albeit small association (HR = 1.08), and as previously noted, this effect estimate is likely biased toward the null because of nondifferential misclassification of exposure.

Id. at 13.

As set forth more fully below, these methods (and results) were not only reviewed by NIH, but peer-reviewed by the Journal of Clinical Oncology several times before publication on May 15, 2024. Moreover, the article, its methods, and results were reviewed and featured several times *after* publication, including by NIH in its press release, Ex. 2; Drs. Harris, David, and Terry, who were invited to write the invited editorial on the paper, Ex. 3; and also by the American Society of Clinical Oncologists, Ex. 15, *Study Finds Association Between Genital Talc Use and Increased Risk of Ovarian Cancer*, ASCO (May 15, 2024).

III. Dr. Kornak's rushed critique is entitled to no deference and little weight.

John Kornak, Ph.D. is a professor of biostatistics at the University of California—San Francisco. He was hired by J&J to critique the peer-reviewed methods used by the independent NIH investigators in O'Brien 2024. His litigation report, Ex. 5, was hastily drafted in a matter of days, between May 20 and 28 of this year. In his report, Kornak accuses the NIH authors of "guess[ing]" and "speculat[ing]" about missing data, *id*. at 18 ¶ 40, 26 ¶ 59, calling into question the validated multiple imputation methodology they used. Along the way, he parrots J&J talking points, using nonscientific phrases like "flawed and unreliable," "contrived," and "vacuous." *Id*. at 35 ¶ 72, 36 ¶ 74. These are the hallmarks of an advocate, not a scientist.

The very circumstances surrounding Dr. Kornak's report suggest unreliability. O'Brien 2024 was published on May 15, 2024. Within days of O'Brien 2024's publication, Dr. Kornak was contacted by the Cornerstone company retained by J&J's lawyers to address O'Brien's methods. (Ex. 6, Kornak Dep. 16:2–11.) He got a copy of O'Brien 2024 on May 20, which was the same day he met with J&J's lawyers. *Id*. at 21:9–14. He hadn't even read the full paper before talking with the attorneys—and in fact, even today, he's not sure if he has "*ever* read it from start to finish." *Id.* at 26:4–23, 48:24–49:12 (emphasis added). Despite that lack of understanding, he understood that the goal of the May 20 meeting was to hire him to write a litigation report by May 28, which he agreed to do. *Id*. at 22:10–18.

By May 22—meaning, within two days of meeting with the lawyers, and *less than* two days of reading any piece of O'Brien 2024 for the first time, Dr. Kornak had formulated his opinions that the article written by these preeminent NIH Scientists had "problems." *Id.* at 55:2–16. Dr. Kornak was not sure when he (or others) had formulated the descriptive words "flawed and unreliable," but his testimony was that he probably had reached *that* opinion by May 23. *Id.* at 50:6–12, 51:18–53:16, 58:5–18.

Dr. Kornak didn't write his report all by himself. In fact, he met with or had calls with Cornerstone, the expert search company, on May 20, 21, 22, 26, 27, 28, and 29. *Id*. at 45:6–16. Cornerstone did some of his research for him. *Id*. at 48:2–9. Dr. Kornak finalized his litigation report and signed it eight days after being hired, on May 28. *Id*. at 24:3–14.

While the report itself covers multiple issues and criticisms, most of the report focuses on O'Brien 2024's quantitative bias assessment. Specifically, Dr. Kornak focuses on the authors' use of multiple imputation—one of their quantitative bias tools—to address women who were not able to complete the supplemental questionnaire on lifetime talc use. At his core, Dr. Kornak believes that O'Brien 2024 should have used only the Sister Study enrollment questionnaire talc use data "as is," Ex. 5, Kornak Rep. 13 ¶ 28, and should have wholly *ignored* the talc use data on lifetime talc use from the supplemental questionnaire, *id*. at 13–14 ¶¶ 28–31. Put another way, Dr. Kornak advocated using talc use data which even *he admitted* included only four years of talc

use data (ages 10–13 and one year before enrollment) and calling it "'ever' use" data. *Id.* at 14 ¶ 30. He does not dispute that his approach would have excluded dozens of years of talc use data collected from women on the supplemental questionnaire. Astonishingly, he further advocated that the O'Brien 2024 authors should have (mis)represented the four years' use result as their "main result." *Id.* at 14 ¶ 31. While Kornak agreed that his proposal to ignore some of the available use data would have been misleading, that did not bother him. He testified: **"Why ruin a perfectly good analysis by throwing your [imputation] calculations in?"** (Ex. 6, Kornak Dep. 283:5–9, 283:5–289:22 (fuller discussion).)

Separately, Kornak testified that he had not read key articles before formulating his slanted opinions. One such article, published by White and Royston, Ex. 14, was the sole methods paper cited by the O'Brien 2024 authors to support their multiple imputation model. *Kornak failed to cite or even fully read it.* (Ex. 6, Kornak Dep. 320:15–321:1 ("**I looked at it. I didn't go through it in detail.**").) Since that was the only paper cited by the authors in support of their multiple imputation model, Kornak was given a break during his deposition to read it. Despite this allowance for Kornak to read this critical study, he testified that, during the deposition break, he merely scanned it. *Id.* at 324:12–325:5 ("**I had an opportunity to scan it . . . just from now, my quick look, you know, that would be a paper that would take days to carefully look at**").

That's a concession, by the way, from Dr. Kornak that he wrote his own report, criticizing O'Brien 2024, without taking the "days" it would take to understand the foundation of their work. This is not sound science.

Similarly, Dr. Kornak's Report cited another Sister Study paper by Chang, O'Brien and others,[9] in support of several of his key opinions. (Ex. 5, Kornak Rep. 25 ¶ 54 (citing Chang).) But on questioning, he admitted that: "**I don't think I read it completely . . . I assumed I looked at the paper.**" (Ex. 6, Kornak Dep. 393:10–20.)

Kornak's abject failure to actually read key methodologic articles—particularly the methods paper relied on by the O'Brien authors—the incendiary language used throughout the report, and the fact that there were almost daily meetings with the "legal team" or "Cornerstone" in the eight days leading to the filing his report raises the specter that parts of his report were actually written by, or at least guided by, J&J's lawyers and their contractor.

Ultimately, Kornak expresses a hindsight opinion that takes issues with:

- The independent NIH Sister Study—a study and authors J&J previously vouched for: "I mean obviously I'm sitting here in a position where I can retrospectively pontificate about what I would have done. But . . . you really ought to have designed the study in the first place to answer the questions you want to answer." *Id*. at 284:18–286:5;

[9] Chang, C. J., O'Brien, K. M., Keil, A. P., Goldberg, M., Taylor, K. W., Sandler, D. P., & White, A. J., *Use of personal care product mixtures and incident hormone-sensitive cancers in the Sister Study: a US-wide prospective cohort*, Environment Int'l, 183, 108298 (2024), *available at* https://doi.org/10.1016/j.envint.2023.108298.

- The peer review process which confirmed and validated the researchers' work**: "I am frankly stunned that the peer-review process did not catch this catch the problems in this analysis.**" *Id.* at 363:17-22 (emphasis added); and

- The NIH itself, which featured the article: **"I don't believe that these people have in any way examined the methods in the paper."** *Id*. at 178:4–6.

IV. Argument.

The Court should exclude Kornak's testimony for two reasons. First, the O'Brien 2024 study contained a scientifically accepted methodology that deserves deference. Second, Kornak fails both the reliability and fit prongs of admissible expert testimony.

A. The "quantitative bias analysis" methods of the O'Brien 2024 study deserve deference.

As discussed in detail, O'Brien 2024 was a peer-reviewed scientific study that fully disclosed a reliable methodology. "The fact that a study has been subject to peer review 'does not equate with reliability,' but it does suggest that good science was used by the authors." *In re Johnson & Johnson*, 509 F. Supp. 3d 116, 143 (D.N.J. 2020) (emphasis added); *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993) ("submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected.").

Recognizing that the methods employed by the independent O'Brien 2024 authors passed multiple levels of peer review, Dr. Kornak suggests that this courtroom might be

the best place to challenge the methods employed by the experienced NIH researchers because, in his view, he "do[es not] know if peer review resolves complex scientific issues." (Ex. 6, Kornak Dep. 184:23-185:8.) Astonishingly, Dr. Kornak wants to bring his *non-peer-reviewed* opinions to this Court because the peer reviewers "missed it," *id.* at 166:18–167:2; the associate editor of the Journal of Clinical Oncology "ignored it," *id.* at 167:4–8; the NIH "didn't examine" it, *id.* at 177:7–178:6; and the American Society of Clinical Oncology "took what's in O'Brien at face value," *id.* at 187:3–23.

Kornak's haphazard rebuke is simply not how courts in this Circuit look upon the peer review process. *See e.g., Kolokowski v. Crown Equip. Corp.*, No. 05-4257, 2009 WL 2857957, at *10 (D.N.J. Aug. 27, 2009) (noting that "the dearth of peer reviewed literature counsels against the admission of" an expert). This is particularly true for an article like O'Brien 2024, which carries multiple indicia of reliability. Its authors are independent, senior researchers at NIH; they have published on talc and ovarian cancer since 2016. The article was submitted for peer review to the *Journal of Clinical Oncology* in September 2023, received that peer review, was revised in response to comments from the review, was resubmitted in January 2024, and was accepted for publication in March 2024. (Ex. 16, O'Brien 2024 Publication History.) Even then, NIH had to review the final pre-publication copy before it was published on May 15, 2024. (Ex. 6, Kornak Dep. 170:7-15.) In conjunction with that, the Harris authors wrote their editorial on its methods, Ex. 3; the NIH publicized the article, Ex. 2; and even the

American Society of Gynecologic Oncology amplified the study, Ex. 15. This is a robust peer review and approval process by anyone's lights.

Ultimately, O'Brien 2024's multiple peer review steps are an emblem of "good science," *In re Johnson & Johnson*, 509 F. Supp. 3d at 143, and the study should be given deference by the Court.

B. Dr. Kornak's litigation-created report is biased and not reliable.

The facts surrounding Kornak's drafting of his opinion lay the foundation of unreliability and inappropriate bias. An expert opinion that presents conclusions without any support, or "evidence that is connected to existing data only by the *ipse dixit* of the expert," may be excluded as unreliable. *Gen. Elec. Co. v. Joiner*, 522 U.S. 137, 146 (1997); *see also In re Johnson & Johnson*, 509 F. Supp. 3d at 194 (ignoring "highly relevant" evidence warrants exclusion). "If an opinion is fundamentally unsupported, then it offers no expert assistance to the jury." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 421 (5th Cir. 1987).

With the involvement of both J&J's legal team and Cornerstone, Dr. Kornak formulated an unsupported opinion that O'Brien 2024 multiple imputation technique had "problems." Indeed, Dr. Kornak agreed to write his litigation report before he fully read O'Brien 2024. Dr. Kornak's report is chock full of superlatives and is more akin to one of J&J's legal briefs than to a scholarly paper. Without support, Kornak calls aspects of the paper "flawed," "contrived," "vacuous" and claims that the peer reviewers, including

NIH, did not see what he saw. But despite this Dr. Kornak's self-proclaimed confidence, he has "no intention" of ever expressing his opinions "outside the Courtroom." (Ex. 6, Kornak Dep. 404:17–22.)

Dr. Kornak's methods in his assignment here were slapdash and not representative of considered science. In Dr. Kornak's deposition, he first suggested that he had written on multiple imputation in two articles on his curriculum vitae. However, when confronted with fact that neither paper even mentions "imputation," he backtracked. *Id.* at 93:17–97:15. Dr. Kornak even testified that he failed to read key papers that he was provided and claimed to have relied upon in his report. *Id.* at 26:11–16, 320:15–321:1, 324:12–325:8.

A particularly important illustration of the slapdash way Dr. Kornak approached his charge is highlighted in his criticism of the O'Brien 2024 author's decision to include "cancer outcomes" in their imputation model. (Ex. 5, Kornak Rep. 25–26 ¶¶ 56–58.) Kornak was clear that this was one of his main criticisms of O'Brien 2024. (Ex. 6, Kornak Dep. 301:3–8.) According to his testimony, including cancer status (ovarian cancer) in the imputation model was a fatal flaw, because it created a "feedback loop" and generates a larger hazard ratio. (Ex. 5, Kornak Rep. 25 ¶ 57; Ex. 6 Kornak Dep. 310:3–314:17.) Kornak chided the O'Brien authors—and by extension, all the peer reviewers—for making an error he claims falsely "prop[ped] up" the association and renders their conclusions "unverifiable." (Ex. 5, Kornak Rep. 25–26 ¶¶ 57–58.)

The problem with Kornak's criticisms of O'Brien's inclusion of cancer status in the imputation model is that his criticism is demonstrably wrong (and for a sloppy reason). Not only does Kornak not cite any authority for the proposition that "cancer status" should not have been included in their imputation model, but he also did not address (or even know) the O'Brien 2024 authors cited authority for *including* it. (Ex. 6, Kornak Dep. 314:18–316:23.) The paper that O'Brien cited for including ovarian cancer in the model is the one by White and Royston, Ex. 14, and is clearly set forth in O'Brien 2024's methods section, Ex. 1 at 4 n.32.

When asked about this, Kornak admitted that the authors cited it:

> Q. All right. And you don't discuss that paper at all in your report, do you?
>
> A. No.
>
> . . .
>
> Q. Okay. And this is the paper upon which the authors rely for including cancer status in their multiple imputation model, correct?
>
> A. I think they use the paper to try and point out—to kind of, like, say what the method is that they're using for kind of incorporating that data rather than as a justification, but—
>
> Q. Well, they're basically saying we applied, we applied a multiple imputation methodology that was in the published literature and here it is at footnote 42 for the world to see, right? They just didn't say it without attribution, true?

> A. Yeah, again, they're just saying this is the way they dealt with incorporating the outcome into their imputation log.

(Ex. 6, Kornak Dep. 315:10–316:23.)

Contrary to Kornak's unsupported assertion that cancer status should not have been used in the imputation model, White and Royston make clear that the association being assessed—in this case ovarian cancer—**must be included in the imputation model, just as O'Brien 2024 stated it should:**

> The choice of variables in the imputation model is crucial: *in particular, any association to be assessed in the analysis model must be allowed for in the imputation model,* for otherwise bias towards the null is likely. When the incomplete data are covariates in the analysis model, the analysis model outcome must be used to predict the missing covariate values. *Although this practice may seem counter-intuitive, it is in fact essential.*

(Ex. 14, White and Royston, at 1983 (emphasis added).)

When confronted with this clear omission, Kornak stated that he would **"really have to sit down and look at the context"**—which he had failed to do before signing his report. (Ex. 6, Kornak Dep. 320:10-14.) The fact that Dr. Kornak had not even read O'Brien 2024's justification for including cancer status in their imputation model—much less addressed it—is but one example of the carelessness and thoughtlessness he employed throughout his report.

V. Conclusion.

Dr. Kornak's proffered testimony is based entirely on speculation and constitutes textbook *ipse dixit* that courts do not allow. Since Dr. Kornak cannot substantiate or support his proffered testimony, it should not be heard by any jury.

For these reasons, the Court should exclude the opinions and testimony of Dr. Kornak. The PSC further requests that the Court accept and consider the rebuttal report of Dr. Stuart, Ex. 7, to address J&J's criticisms of O'Brien 2024.

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